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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/921,655	08/03/2001	Michael H. Cardone	M00925/70106	5833

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EXAMINER

CHEU, CHANGHWA J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/921,655	Applicant(s) CARDONE ET AL.	
	Examiner Jacob Cheu	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 73 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicant's amendment filed on 5/6/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 11-72 are cancelled.
2. Claim 1 is amended.
3. Currently, claims 1-10, 73-74 are under examination.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claim 1, 3, 4, 6, 7, 8 are rejected under 35 U.S.C. 102(e) as being anticipated by Wagner et al. (US 6475808).

Wagner et al teach a protein array for in vitro screening biomolecular activities. Wagner et al teach covalently immobilizing proteins to the solid support of the array, i.e. organic thinfilm (Col. 7, line 35-45). The covalent immobilization include, maleimide, N-hydroxysuccinimide conjugation on the solid substrate (Col. 16, line 60-67). The solid support materials can be of glass (Col. 7, line 8-12). Wagner et al also teach an antibody array with antibody fragments against known antigens (Col. 25, line 22-28). Examiner takes the position to interpret the claim broadly because applicant further limits the "linker molecule" with merely functional moieties, such as maleimide, vinyl sulfonate or hydroxy succinimide groups. Examiner considers that the covalent binding in Wagner et al reference is a linker molecule itself with various functional moieties.

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Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 2, 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. in view of Sakata et al. (EP 0140489) and Bagchi et al.. (US 4855219)

Wagner et al reference has been discussed but does not explicitly teach covalently binding linker such as vinyl sulfone, carboxy groups. Sakata et al. teach using covalent modification for increasing immunodetection, including adding hydroxyl, carboxyl, succinimide or sulfhydryl groups. (page 5, line 18-22; 6, line 5 to page 7, line 1-15) Similarly, Bagchi et al. also teach using compounds containing vinyl sulfone groups for cross-linking purposes on the solid support, i.e. microplate (Col. 3, line 12-18) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Wagner et al with the methods of covalent immobilization method for attachment of the protein or antibody in the microarray as taught by Sakata and Bagchi et al because covalent modifications on a solid phase in

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increasing sensitivity of immunoassay is well-known in the art and different compounds used for covalent modifications on the solid support have been developed in the fields, such as adding the vinyl sulfone, carboxy, N-hydroxy succinimide groups.

5. Claims 9-10 and 73-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wagner et al in view of MacBeath et al. (J. Am. Chem. Soc. 1999 121: 7967-7968)

Wagner et al reference has been discussed but does not explicitly teach microarray and the density of the microplates for screening samples. MacBeath et al. teach a microarray having microwell density of 2000 spots per cm^2 for mass screening purposes (See Figure 4) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Wagner et al with the microarray having a high density as taught by MacBeath et al since the mass screening is the ultimate purpose in microarray and arrangement of density for array more samples involves only skill in the art.

Response to Applicant's Arguments

1. Applicant's arguments with respect to claims 1-10, 73-74 have been considered but are moot in view of the new ground(s) of rejection.
2. The rejections of claims 1, 3, 4, 7-8 under 35 U.S.C. 102 (b) as being anticipated Bosslet et al is withdrawn.
3. The rejections of claims 2, 5, 6 under 35 U.S.C. 103(a) as being unpatentable over Bosslet et al. in view of Sakata et al. and Sakata i et al is withdrawn.
4. The rejections of claims 9-10, 73-74 under 35 U.S.C. 103(a) as being unpatentable over Bosslet et al in view of MacBeath et al is withdrawn.

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Linker

With respect to the newly amendment in claim 1, "a linker molecule" covalently attached to the said solid support, Applicant defines linker as "a chemical moiety which covalently joins the reactive groups already on the substrate and the binding element to be eventually immobilized, having a backbone of chemical bonds forming a continuous connection between the reactive groups on the substrate and the binding elements, and having a plurality of freely rotating bonds along that backbone." (See page 8, second paragraph) Examiner had pointed out in this Office Action that the covalent modifications on the solid supports in Wagner, or Sakata and Sakata references are "linker molecules" attached to the solid support and joining to the protein (or antibody) for microarray. Therefore, Wagener et al reference anticipates the instant claims 4 and 6, and together with Bosslet and Bachagi render claims 2 and 5 obvious.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

Examiner

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LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

September 15, 2004

09/20/04